

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

Display Date	1-18-00
Publication Date	1-19-00
Certifier	SNKese

Food and Drug Administration

[Docket Nos. 91N-0101, 91N-0098, 91N-0103, and 91N-100H]

Food Labeling; Health Claims and Label Statements; Request for Scientific Data and Information; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for written comments; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 75 days the comment period for the submission of scientific data, research study results, and other related information on four substance-disease relationships that was announced in the **Federal Register** of September 8, 1999 (64 FR 48841). This action is being taken in response to requests for more time to submit data and information to FDA.

DATES: Written comments by *[insert date 75 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine J. Lewis, Center for Food Safety and Applied Nutrition (HFS-451), Food and Drug Administration, 200 C. St. SW., Washington, DC 20204, 202-205-4168.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 8, 1999 (64 FR 48841), FDA requested scientific data, research study results, and other related information on four substance-disease relationships in order to reevaluate the scientific evidence for these relationships.

FDA stated that it was taking this action to comply with a recent court decision in which FDA

was instructed to reconsider whether to authorize health claims for these relationships in dietary supplement labeling. The four health claims are: "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer," "Consumption of fiber may reduce the risk of colorectal cancer," "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease," and "0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form." The agency stated that it will use the data and information to determine, for each substance-disease relationship, if an appropriate scientific basis exists to support the issuance of a proposed rule to authorize a health claim for the relationship.

The agency received requests to reopen the comment period on the September 8, 1999, notice to allow interested persons to comment after reviewing FDA's guidance on the "significant scientific agreement" standard for health claims in 21 U.S.C. 343(r)(3)(B)(i) and 21 CFR 101.14(c). The availability of that guidance was announced on December 22, 1999 (64 FR 71794). The agency has agreed to reopen the comment period on the September 8, 1999, notice for 75 days in response to the requests.

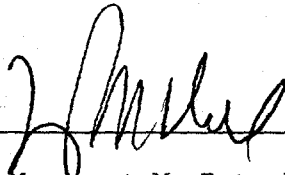
The agency has established four dockets to compile information relating to each of the four topic areas; docket numbers are specified in Table 1 below. FDA is allowing 75 days for the submission of additional data. Individuals and organizations submitting information or data relating to a specific topic should submit two copies of the information to the Dockets Management Branch (address above) by *[insert date 75 days after date of publication in the **Federal Register**]*. Separate submissions should be made for each topic area, and each submission should be identified with the appropriate docket number given below. Submissions received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Scientific data, research study results, and other related information on four substance-disease relationships that is submitted to the FDA must be considered publicly available. If used in the

TABLE 1.

Topic	Docket No.
Antioxidant vitamins and cancer	91N-0101
Fiber and colorectal cancer	91N-J098
Omega-3 fatty acids and coronary heart disease	91N-0103
Folic acid (dietary supplement vs. food form) and neural tube defects	91N-100H

Dated: 1/11/00
January 11, 2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy

14 00 00
[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

